



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Mark A. Tracy, Kevin L. Ward and Warren E. Jaworowicz  
Application No.: 10/773,124 Group Art Unit: 1615  
Filed: February 5, 2004 Examiner: Not Assigned  
Confirmation No.: 3258  
Title: METHOD OF PRODUCING SUBMICRON PARTICLES OF A LABILE AGENT AND USE THEREOF

| CERTIFICATE OF MAILING OR TRANSMISSION  |                            |
|---|----------------------------|
| I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as First Class Mail in an envelope addressed to Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, or is being facsimile transmitted to the United States Patent and Trademark Office on: |                            |
| 7/7/04  | <i>Christina McSweeney</i> |
| Date  | Signature                  |
| <i>Christina McSweeney</i>  |                            |
| Typed or printed name of person signing certificate   |                            |

INFORMATION DISCLOSURE STATEMENT

Mail Stop Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

This Information Disclosure Statement is submitted:

- ☐ under 37 CFR 1.129(a), or  
(First/Second submission after Final Rejection)
- ☒ under 37 CFR 1.97(b), or  
(Within any one of the following time periods: three months of filing national application (other than a CPA) or date of entry of the national stage in an international application; or before the mailing date of a first office action on the merits in a non-provisional application, including a CPA, or a Request for Continued Examination).
- ☐ under 37 CFR 1.97(c) together with either:
- ☐ a Statement under 37 CFR 1.97(e), as checked below, or
- ☐ a \$180.00 fee under 37 CFR 1.17(p), or  
(After the 37 CFR 1.97(b) time period, but before final action or notice of allowance, whichever occurs first)
- ☐ under 37 CFR 1.97(d) together with:
- ☐ a Statement under 37 CFR 1.97(e), as checked below, and
- ☐ a \$180.00 fee under 37 CFR 1.17(p), or  
(Filed after final action or notice of allowance, whichever occurs first, but on or before payment of the issue fee)
- ☐ under 37 CFR 1.97(i):  
Applicant requests that the IDS and cited reference(s) be placed in the application filewrapper.  
(Filed after payment of issue fee)

Statement Under 37 CFR 1.97(e)

- ☐ Each item of information contained in this Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement; or
- ☐ No item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the undersigned, after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of this Information Disclosure Statement.

Statement Under 37 CFR 1.704(d) (Patent Term Adjustment)

Applies to original applications (other than design) filed on or after May 29, 2000

- ☐ Each item of information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart application and this communication was not received by any individual designated in § 1.56(c) more than thirty days prior to the filing of the Information Disclosure Statement.
- ☒ Enclosed herewith is form PTO-1449:
- ☐ Copies of the cited references are enclosed.
- ☒ Since this application was filed after June 30, 2003, copies of issued U.S. patents and published U.S. applications are not required and are not being provided.
- ☒ Copies of the cited references are enclosed except those entered in prior application, U.S. Application No. 09/321,091, to which priority under 35 U.S.C. 120 is claimed. The earlier application contains copies of the cited references.
- ☐ The listed references were cited in the enclosed International Search Report in a counterpart foreign application.
- ☐ The "concise explanation" requirement (non-English references) for reference(s) ☐ under 37 CFR 1.98(a)(3) is satisfied by:
- ☐ the explanation provided on the attached sheet.
- ☐ the explanation provided in the Specification.
- ☐ submission of the enclosed International Search Report.
- ☐ submission of the enclosed English-language version of a foreign Search Report and/or foreign Office Action.
- ☐ the enclosed English language abstract.

☐ Applicant requests that the following non-published pending applications be considered:

Examiner's  
Initials

\_\_\_\_\_ U.S. Patent Application No. [ ], by [inventor(s)], filed [ ], Docket No.: [ ]

\_\_\_\_\_ U.S. Patent Application No. [ ], by [inventor(s)], filed [ ], Docket No.: [ ]

\_\_\_\_\_ U.S. Patent Application No. [ ], by [inventor(s)], filed [ ], Docket No.: [ ]

\_\_\_\_\_  
Examiner

\_\_\_\_\_  
Date

- ☐ A copy of each above-cited application, including the current claims, is enclosed.
- ☐ A copy of each above-cited application, including the current claims, is enclosed, except those entered in prior application, U.S. Application No. [ ], to which priority under 35 U.S.C. 120 is claimed.

The Examiner is requested to return a copy of the above list of pending applications indicating which references were considered with the next office communication.

It is requested that the information disclosed herein be made of record in this application.

Method of payment:

- ☐ A check for the fee noted above is enclosed, or the fee has been included in the check with the accompanying Reply. A copy of this Statement is enclosed.
- ☐ Please charge Deposit Account 08-0380 in the amount of \$[ ]. A copy of this Statement is enclosed.
- ☒ Please charge any deficiency in fees and credit any overpayment to Deposit Account 08-0380.

Respectfully submitted,

HAMILTON, BROOK, SMITH & REYNOLDS, P.C.

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Concord, MA 01742-9133

Dated: July 7, 2004

PTO-1449 REPRODUCED

INFORMATION DISCLOSURE CITATION  
IN AN APPLICATION

July 7, 2004

(Use several sheets if necessary)

ATTORNEY DOCKET NO.  
1733.1045-008APPLICATION NO.  
10/773,124FIRST NAMED INVENTOR  
Mark A. TracyFILING DATE  
February 5, 2004EXAMINER  
Not AssignedCONFIRMATION NO.  
3258GROUP  
1615

## U.S. PATENT DOCUMENTS

| EXAM-<br>INER<br>INI-<br>TIAL | REF.<br>NO. | DOCUMENT NUMBER<br>Number-Kind Code (if known) | ISSUE DATE /<br>PUBLICATION DATE<br>MM-DD-YYYY | NAME OF PATENTEE OR APPLICANT<br>OF CITED DOCUMENT |
|-------------------------------|-------------|--|--|--|
|                               | AA          | 5,307,640                                      | 03 MY 94                                       | Fawzy, <i>et al.</i>                               |
|                               | AB          | 5,475,984                                      | 19 DEC 95                                      | Fermani, <i>et al.</i>                             |
|                               | AC          | 5,399,363                                      | 21 MAR 95                                      | Liversidge, <i>et al.</i>                          |
|                               | AD          | 5,145,684                                      | 08 SEP 92                                      | Liversidge, <i>et al.</i>                          |
|                               | AE          | 5,518,187                                      | 21 MAY 96                                      | Bruno, <i>et al.</i>                               |
|                               | AF          | 5,591,456                                      | 07 JAN 97                                      | Franson, <i>et al.</i>                             |
|                               | AG          | 5,817,343                                      | 06 OCT 98                                      | Burke  |
|                               | AH          | 5,711,968                                      | 27 JAN 98                                      | Tracy, <i>et al.</i>                               |
|                               | AI          | 5,716,644                                      | 10 FEB 98                                      | Zale, <i>et al.</i>                                |
|                               | AJ          | 5,667,808                                      | 16 SEP 97                                      | Johnson, <i>et al.</i>                             |
|                               | AK          | 5,674,534                                      | 07 OCT 97                                      | Zale, <i>et al.</i>                                |
|                               | AA2         | 5,656,297                                      | 12 AUG 97                                      | Bernstein, <i>et al.</i>                           |
|                               | AB2         | 5,540,937                                      | 30 JUL 96                                      | Billot, <i>et al.</i>                              |
|                               | AC2         | 5,019,400                                      | 28 MAY 91                                      | Gombotz, <i>et al.</i>                             |
|                               | AD2         | 5,654,010                                      | 05 AUG 97                                      | Johnson, <i>et al.</i>                             |
|                               | AE2         | 5,912,015                                      | 15 JUN 99                                      | Bernstein, <i>et al.</i>                           |
|                               | AF2         | 5,922,253                                      | 13 JUL 99                                      | Herbert, <i>et al.</i>                             |
|                               | AG2         | 5,534,270                                      | 09 JUL 96                                      | De Castro  |
|                               | AH2         | 6,444,223                                      | 03 SEP 02                                      | Tracy, <i>et al.</i>                               |
|                               | AI2         | 6,514,533                                      | 04 FE 03                                       | Burke, <i>et al.</i>                               |
|                               | AJ2         |  |  |  |
|                               | AK2         |  |  |  |
|                               | AA3         |  |  |  |
|                               | AB3         |  |  |  |
|                               | AC3         |  |  |  |

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DATE CONSIDERED

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|---|---------------------------------------|--|---------------------------------|---------------|
| PTO-1449 REPRODUCED<br><br><b>INFORMATION DISCLOSURE CITATION<br/>IN AN APPLICATION</b><br><br><b>July 7, 2004</b><br><br>(Use several sheets if necessary) | ATTORNEY DOCKET NO.<br>1733.1045-008  |  | APPLICATION NO.<br>10/773,124   |               |
|   | FIRST NAMED INVENTOR<br>Mark A. Tracy |  | FILING DATE<br>February 5, 2004 |               |
|   | EXAMINER<br>Not Assigned              |  | CONFIRMATION NO.<br>3258        | GROUP<br>1615 |

## FOREIGN PATENT DOCUMENTS

|  |     | DOCUMENT NUMBER<br>Country Code-Number-Kind Code<br>(if known) | DATE<br>MM-DD-YYYY | NAME OF PATENTEE OR APPLICANT<br>OF CITED DOCUMENT | TRANSLATION<br>YES NO |  |
|--|-----|--|--------------------|--|-----------------------|--|
|  | AL  | WO 95/31973  | 30 NOV 95          | Eastman Kodak Company                              |                       |  |
|  | AM4 | WO 90/13780  | 15 NOV 90          | Enzytech, Inc.                                     |                       |  |
|  | AN  | WO 90/13285  | 15 NOV 90          | Enzytech, Inc.                                     |                       |  |
|  | AO  | WO 95/29664  | 09 NOV 95          | Alkermes Controlled<br>Therapeutics, Inc.          |                       |  |
|  | AP  | WO 97/42940  | 20 NOV 97          | Alkermes, Inc.                                     |                       |  |
|  | AQ  | EP 0330180 A1  | 30 AUG 89          | Biomaterials Universe, Inc.                        |                       |  |
|  | AP2 | EP 0499299 A2  | 19 AUG 92          | NanoSystems L.L.C.                                 |                       |  |
|  | AM2 |  |                    |  |                       |  |
|  | AN2 |  |                    |  |                       |  |
|  | AO2 |  |                    |  |                       |  |
|  | AP2 |  |                    |  |                       |  |
|  | AQ2 |  |                    |  |                       |  |
|  | AL3 |  |                    |  |                       |  |
|  | AM3 |  |                    |  |                       |  |
|  | AN3 |  |                    |  |                       |  |
|  | AO3 |  |                    |  |                       |  |
|  | AP3 |  |                    |  |                       |  |
|  | AO3 |  |                    |  |                       |  |
|  | AL4 |  |                    |  |                       |  |
|  | AM4 |  |                    |  |                       |  |
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| PTO-1449 REPRODUCED<br><br><b>INFORMATION DISCLOSURE CITATION<br/>IN AN APPLICATION</b><br><br><b>July 7, 2004</b><br><br>(Use several sheets if necessary) | ATTORNEY DOCKET NO.<br>1733.1045-008  |                          | APPLICATION NO.<br>10/773,124   |  |
|   | FIRST NAMED INVENTOR<br>Mark A. Tracy |                          | FILING DATE<br>February 5, 2004 |  |
|   | EXAMINER<br>Not Assigned              | CONFIRMATION NO.<br>3258 | GROUP<br>1615                   |  |

**OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)**

|     |  |
|-----|--|
| AR  | "Drug Nanocrystals for Improved Drug Delivery of Poorly Water Soluble Compounds", Presentation at CRS Meeting, Kyoto Japan 7/11/1996, Pages 1-50 by G. Liversidge and E. Cooper. |
| AS  |  |
| AT  |  |
| AU  |  |
| AV  |  |
| AW  |  |
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